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Record List Display Page 1 of 1

Summary of Invention Paragraph:

[0074] "Local administration" means direct administration of a pharmaceutical at or to the vicinity of a site on or within an animal body, at which site a biological effect of the pharmaceutical is desired. Local administration excludes systemic routes of administration, such as intravenous or oral administration.

Record List Display Page 1 of 1

Detail Description Paragraph:

[0084] The present invention is based on the discovery that <u>intracranial</u> administration of a neurotoxin can provide significant and long lasting relief from a variety of different neuropsychiatric disorders. <u>Intracranial</u> administration permits a neurotoxin to be locally administered at a site, <u>within</u> a patient's cranium, that has a direct effect on the neurons involved in the disorders, and avoids complications associated with passage of the neurotoxin across the blood brain barrier. Thus, <u>intracranial</u> administration provides greater local dosages of a neurotoxin to a brain area than is achieved with systemic routes of administration, and avoids the non-specificity associated with systemic administration of current therapeutic agents. Indeed, systemic administration of a neurotoxin, such as a botulinum toxin, is contraindicated due to the severe complications (i.e. botulism) which can result from entry of a botulinum toxin into the patient's general circulation.

DOCUMENT-IDENTIFIER: US 6746669 B1

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TITLE: Method for down-regulating IL5 activity

CLAIMS:

- 10. The method according to claim 9, wherein the natural T-helper lymphocyte epitope is selected from a <u>tetanus</u> toxoid epitope, a diptheria toxoid epitope, an influenza virus hemagluttinin epitope, and an epitope of P. falciparum circumsporozoite (CS) protein.
- 18. The method according to claim 17, wherein the adjuvant is selected from the group consisting of an immune targeting adjuvant; a toxin; a cytokine; a mycobactexial derivative; an oil formulation; a polymer; a micelle forming adjuvant; a saponin, an immunostimulating complex matrix (an ISCOM matrix); a particle; dimethyldioctadecylammonium bromide, aluminium adjuvants; DNA adjuvants; .gamma.-insulin; and an encapsulating adjuvant.
- 19. The method according to claim 1, wherein an effective amount of the modified IL5 polypeptide is administered to the animal via a route selected from the parenteral route; the peritoneal route; the oral route; the buccal route; the sublinqual route; the epidural route; the spinal route; the anal route; and the intracranial route.
- 24. The method according to claim 10, wherein the <u>tetanus</u> toxoid epitope is selected from the group consisting of P2 and P30.
- 34. An immunogenic composition according to claim 33, wherein the adjuvant is selected from the group consisting of an immune targeting adjuvant; a toxin; a cytokine; a mycobacterial derivative; an oil formulation; a polymer, a micelle forming adjuvant; a saponin; an immunostimulating complex matrix (an ISCOM matrix); a particle; dimethyldioctadecylammonium bromide; aluminium adjuvants; DNA adjuvants; .gamma.-inulin; and an encapsulating adjuvant.

- (b) injecting the <u>neurotoxin</u> into the subarachnoid space.
- 31. A method for the in vivo attenuation of a nociceptive activity or experience of a human patient, the method comprising the step of intraspinal administration to a human patient a therapeutically effective amount of a botulinum toxin, wherin the botolinum toxin is not attached to a neuronal targeting moiety thereby causing an in vivo attenuation of a nociceptive activity or experience of the human patient, wherein the botulinum toxin is a recombinantly produced botulinum toxin.
- 33. The method of claim 31, wherein the <u>botulinum toxin</u> is selected from the group consisting of modified <u>botulinum toxins</u> A, B, C, D, E, F and G.
- 34. The method of claim 33, wherein the botulinum toxin is a botulinum toxin type A.
- 35. A method for treating pain, the method comprising the steps of:
- (a) selecting a <u>neurotoxin</u> free of any neuronal targeting moiety;
- (b) choosing a portion of an intraspinal region of a patient which influences pain;
- (c) intraspinally administering an effective amount of the <u>neurotoxin</u> selected, thereby alleviating pain experienced by the patient, wherein the <u>neurotoxin</u> is a recombinant produced <u>botulinum toxin</u>.
- 36. A method for treating pain, the method comprising the step of administering an effective amount of a pharmaceutical preparation to an intraspinal region or to a dorsal root ganglion of a mammal, thereby alleviating pain experienced by the mammal, wherein the pharmaceutical preparation comprises a neurotoxin which is free of any neuronal targeting moiety and wherein the neurotoxin is a recombinantly produced botulinum toxin.

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